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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/731,683

12/08/2003

Art Bertolero

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20350 7590 11/13/2008  
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EXAMINER

HOPKINS, CHRISTINE D

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

11/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/731,683	<b>Applicant(s)</b> BERTOLERO ET AL.	
	<b>Examiner</b> CHRISTINE D. HOPKINS	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20-29,32-61,63 and 67-71 is/are pending in the application.
- 4a) Of the above claim(s) 24-29,35,36,46-52 and 57-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-23,32-34,37-45,53-56,63 and 67-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 October 2008 has been entered. Claims 20-29, 32-64 and 66-68 are now pending. The Examiner acknowledges the amendments to claims 20, 22, 41, 67 and 68, as well as the cancellation of claims 62, 64 and 66 and the addition of claims 69-71. The indicated allowability of claims 20-29, 32-40, 62-64 and 66-68 is withdrawn in view of the newly discovered reference(s) to Spence et al. (U.S. Patent No. 6,390,976) and Briscoe et al. (U.S. Patent No. 6,758,809). Rejections based on the newly cited reference(s) follow.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

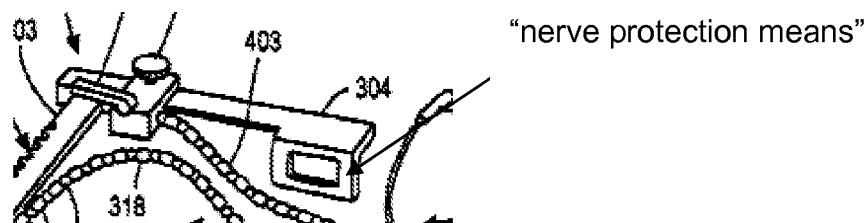
only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 20-22, 32-34, 37-40, 63 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Spence et al. (U.S. Patent No. 6,390,976). Spence et al. (hereinafter Spence) teaches a heart stabilization device. Regarding claims 20 and 69, Spence discloses a surgical system comprising: retractors for accessing a patient's heart through a first incision; a heart stabilizing device **314** having a tissue contacting surface at least one suction aperture adjacent the surface; and a first coupling device **312** for coupling with the heart stabilizing device **314** through a second incision at a location on the patient apart from the first incision, the coupling device comprising: an elongate shaft having a proximal and distal end, and at least one flexible, rigidifying portion **318** comprising a plurality of pieces (beads) and a wire (line) that when tightened locks the pieces of the rigidifying portion into place; and means **316** for coupling the shaft with the heart stabilizing device **314** adjacent the distal end of the shaft (Figs. 11 and 12, and col. 5, lines 62-67 - col. 6, lines 1-46). Regarding claims 21 and 22, the system further includes a heart positioning device **402** having a tissue contacting surface and at least one suction aperture (Figs. 12 and 15); and a second coupling device for coupling with the heart positioning device through a third incision at a location apart from the first and second incisions (Fig. 12). The second coupling device comprises an elongate shaft having a proximal end, a distal end, and at least one flexible, rigidifying portion **403** comprising a plurality of pieces and a wire that when tightened locks the pieces of the rigidifying portion into place, and means for coupling

the elongate shaft with the heart positioning device adjacent the distal end of the shaft (Fig. 12 and col. 7, lines 21-30).

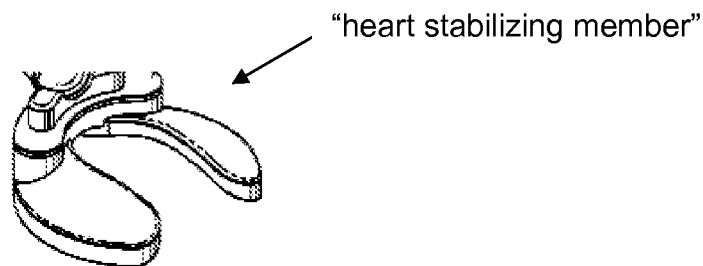
Regarding claim 32, the system further comprises a first flexible arm **324** for coupling the first coupling device with at least one stable object; and a second flexible arm **406** for coupling the second coupling device with the at least one stable object. Elements **324** and **406** are considered to be "flexible" since they are susceptible to adjustment along crossbar **303**. With respect to claim 33, the first and second arms may be "rigidified" by locking with lever **330** and **404**, respectively. With respect to claim 34, the at least one stable object is considered to be "at least one part of an operating room table."

With respect to claims 37 and 39, the retractor device comprises a retractor frame **302** coupled to, and movably holding at least two retractor blades **304**; and crank handle **305** for moving the frame so as to move the blades (Fig. 12 and col. 5, lines 41-55). Regarding claim 38, the lower, rectangular portion of the blade **304** is considered to be the nerve protection means for inhibiting damage to a nerve because it has a cut-out portion which limits contact with the heart tissue (see depiction below).



Regarding claim 40, the heart stabilizing device **200** comprises: at least one tissue contacting surface; at least one suction aperture; and at least one suction port **208** for connecting with a source of suction (Figs. 11, 14 and 15). With respect to claim 63, an actuation device (lever-operated mechanism) is coupled with the first coupling device. A distal coupling means **326**, **328** couples the coupling device with the heart stabilizing device, wherein the actuation device can tighten and loosen the distal coupling means (col. 6, lines 25-27).

4. Claims 41-43, 45, 53, 54, 56 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Fox et al. (U.S. Patent No. 5,865,730). Regarding claims 41, 42, 45, 53, 56 and 70, Fox discloses a device comprising: a heart stabilizing member (or “heart positioning member” in accordance with claim 53) comprising a ball **98**; an elongate coupling member **80** having a proximal end, a distal end, a flexible rigidifying portion comprising a plurality of pieces (beads) and a wire that when tightened locks the pieces into place, and means **85** (“collet”) near the distal end for coupling with the heart stabilizing member, and an actuation device **88** near the proximal end that can tighten the coupling means to the ball of the heart stabilizing member and loosen the coupling means from the ball of the heart stabilizing member (Figs. 13 and 14 and col. 7, lines 32-54).



Regarding claims 43 and 54, the heart stabilizing member comprises: at least one tissue contacting surface; at least one suction aperture for applying suction force; and at least one suction port for coupling with a source of suction (Fig. 12).

5. Claims 67 and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by Briscoe et al. (U.S. Patent No. 6,758,809). Briscoe et al. (hereinafter Briscoe) teaches a system comprising: a retractor device; a heart stabilizing device **21** comprising a tissue contacting surface, a suction aperture and a complementary coupling means; a first coupling device comprising an elongate shaft **20** having a proximal end, a distal end and at least one flexible rigidifying portion comprising a plurality of “beads” and a wire **40** that when tightened locks the pieces of the rigidifying portion into place, a distal coupling means at or near the distal end, and an actuation device **23** at or near the proximal end that can tighten and loosen the distal coupling means, and a first flexible arm **20a** coupled with the first coupling device **20** via a first clamp (turret assembly), wherein the first flexible arm can be rigidified by applying suction (Fig. 1A and col. 3, lines 29-44 - col. 4, lines 1-16 and col. 5, lines 13-46).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spence et al. (U.S. Patent No. 6,390,976) in view of Peng et al. (U.S. Pub. No. 2003/0009080). Spence discloses the invention as claimed, see rejection supra; however Spence fails to disclose that the coupling between the first coupling device and the heart stabilizing device and the second coupling device and the heart positioning shaft is a ball and socket coupling. Peng et al. (hereinafter Peng) teaches an organ manipulator with at least one suction member. Regarding claim 23, Peng teaches that joint coupling the coupling device and heart stabilizing device (suction cup) may be implemented in numerous ways such as a ball joint, hinged joint, pin/slot mechanism, or spring assembly. The necessity is that the joint allows the suction member freedom to move [0068] and provide rotational and translation compliance [0114]. The joint or ball and socket coupling described by Spence provides the same freedom of motion and translational movement (col. 6, lines 2-7). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to have incorporated a ball/collet coupling means as disclosed by Peng into a system for manipulating the heart muscle as suggested by Spence, in order to provide range of motion to the heart tissue during surgery.

8. Claims 44 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (U.S. Patent No. 5,865,730) in view of Houser et al. (U.S. Pub. No. 2003/0060685). Fox discloses the invention as claimed, see rejection supra; however Fox does not teach inflating a tissue contacting surface of the heart stabilizing or positioning member. Houser et al. (hereinafter Houser) teach a surgical instrument for



contacting and stabilizing tissue of the heart. Regarding claims 44 and 55, Houser teaches a heart stabilizing or positioning member **100** having a tissue contacting surface **120**. The contacting section may be configured to provide a variety of atraumatic surfaces, as well as ways to prevent slippage and invoke immobilization of the heart. Houser teaches a member or "port" to supply vacuum, a stream of fluid, or an inflatable medium to abut the contacting section against the surface of the heart [0113]. Furthermore, Houser teaches the introduction of an inflation medium through the same conduit for supplying vacuum, which immobilizes the heart (as in the instant application). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have provided an inflation medium as suggested by Houser to a heart stabilizing or positioning member as taught by Fox such that minimal damage is imparted to the sensitive cardiac tissue.

9. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Briscoe et al. (U.S. Patent No. 6,758,809) in view of Spence et al. (U.S. Patent No. 6,390,976). Briscoe discloses the invention as claimed, see rejection supra; however Briscoe does not disclose the use of a system comprising two sets of coupling devices (arms) and heart stabilizing devices. Spence discloses an additional surgery immobilizer ("heart positioning device") to further support the heart during surgery and isolate a particular area that is to be targeted during surgery (col. 6, lines 47-67 - col. 7, lines 1-12). This device similarly employs a suction cup with apertures in order to immobilize the area (Figs. 12 and 15). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to have incorporated two heart positioning devices as

disclosed by Briscoe, to a heart stabilizing system as taught by Spence, in order to more effectively target and manipulate a particular area of the heart receiving surgical treatment.

### ***Response to Arguments***

10. Applicant's arguments filed 29 October 2008 with respect to the rejection of claims 41-43, 45, 53-54 and 56 under 35 U.S.C. 102(b) citing Fox et al. ('730) have been fully considered but are moot in view of the new grounds of rejection under 35 U.S.C. 102(b) citing Fox et al. ('730) to reflect the amendments made to the claims.

11. Applicant's arguments filed 29 October 2008 with respect to the rejection of claims 44 and 55 under 35 U.S.C. 103(a) citing Fox et al. ('730) in view of Houser et al. (U.S. Pub. No. 2003/0060685) have been fully considered but are moot in view of the new grounds of rejection presented above citing Fox et al. ('730) in view of Houser et al. (U.S. Pub. No. 2003/0060685) to reflect the amendments made to the claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

Art Unit: 3735

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./  
Christine D Hopkins  
Examiner  
Art Unit 3735

/Charles A. Marmor, II/  
Supervisory Patent Examiner  
Art Unit 3735